IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	:	Klautky, et al.
Appl. No.	:	**10/676,568**
Filed	:	September 30, 2003
Title	:	AUTOMATED CYTOLOGICAL SAMPLE CLASSIFICATION
Examiner	:	Lyle Alexander
Group Art Unit	:	1797
Confirm. No.	:	7905

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PETITION FROM REQUIREMENT FOR RESTRICTION UNDER 37 C.F.R. §1.144

Mail Stop Petitions
Commissioner for Patents
P.O. Box 1450
Washington, D.C. 20231

Dear Sir:

This petition under 37 C.F.R. §1.144 is to request withdrawal of the restriction requirement set forth in the Final Office Action dated February 9, 2009. The restriction requirement was traversed in an After-Final response dated March 4, 2009, but was maintained by the Examiner, according to the Advisory Action dated March 24, 2009. Applicants respectfully traverse and request withdrawal of the restriction requirement, for the following reasons:

First, Applicants submit that the restriction requirement is not proper because it is not complete. In particular, the Examiner has not met all of the formal requirements of a restriction requirement since the Examiner has not set forth a reason for insisting upon the restriction (see MPEP §808). Although the Examiner alleges that each of Groups I, II and III is classified

differently, the Examiner has not stated why examination of all of the groups would be burdensome, especially at this stage of the examination history of the present application.

Notably, the Advisory Action fails to address or otherwise correct this deficiency in the restriction requirement. Although the Examiner alleges that claims 30-38 "would require further search and consideration," the Examiner has not set forth any reason on the record as to why there would be a serious burden on the Examiner if restriction is not required.

Second, Applicants respectfully submit that examination of all of the groups would not be burdensome, and that the different classifications of Groups I, II and III proposed by the Examiner are incorrect. For example, the Examiner's classification of Group I in class/subclass 436/177 is inappropriate, because the Group I method of classifying a cytological sample does not include "[l]iberation or purification of sample or separation of material from a sample …." The Examiner's classification of Group III in class 435 ("Chemistry: Molecular Biology and Microbiology"), is also inappropriate, because the Group III method for classifying a cytological sample is more properly classified in class 436 ("Chemistry: Analytical And Immunological Testing"). To the extent that Group II is properly classified in class/subclass 436/63 (testing biological cellular material), class/subclass 436/63 is also the most appropriate classification for Groups I and III. Thus, Applicants submit that Groups I, II, and III are not separately classified and that examination of all of the Groups would not be burdensome. ***Applicants further submit that examination of all of the Groups would not be burdensome because the claims in Groups II and III do not present any additional subject matter that has not presumably already been searched in the examination of Group I.***

In the Advisory Action, the Examiner maintains that the different classifications are proper, but does not address any of the Applicants' arguments regarding classification that were set forth in the After Final response.

Third, the Examiner's allegation that Groups I, II, and III are "related as subcombinations ***disclosed as usable together*** in a ***single combination***" (emphasis added) is incorrect. Independent claim 1 recites a method of classifying a cytological sample which includes providing a cytological sample in solution in a vessel, optically interrogating the solution with at least one wavelength of light, determining whether a result of said interrogation meets a criterion, attaching a positive designator to the sample vessel if the result meets the criterion, and attaching a manipulation designator to the sample vessel if the result does not meet the criterion. Independent claim 30 recites a method of classifying a cytological sample that includes optically interrogating a cytological sample in solution using at least one wavelength of light, determining, based on the interrogation, whether the sample has an adequate concentration of cellular matter needed for performing an intended assay, associating a positive designator with the sample if the sample has an adequate concentration of cellular matter for performing the intended assay, and associating a manipulation designator with the sample if the sample does not have an adequate concentration of cells to perform the intended assay. Independent claim 34 recites a method of classifying a cytological sample suspended in solution that includes optically interrogating the sample using at least one wavelength of light, determining whether a result of said interrogation meets a criterion, associating a positive designator with the sample if the result meets the criterion, and associating a manipulation designator with the sample if the result does not meet the criterion. ***Nowhere in the present specification are the methods of claims 1, 30 and 34 disclosed as usable together.***

In the Advisory Action, the Examiner did not respond to Applicants' argument that Groups I, II, and III are not related as subcombinations disclosed as usable together in a single combination.

Fourth, according to MPEP §817, a proper restriction requirement should include a "short description of total extent of the subject matter claimed in each group" and the Examiner's short descriptions of the subject matter in each of Groups I, II and III are incorrect and misleading. For example, the Examiner describes Group II (claims 30-33) as being drawn to "a method of determining cell concentration." However, while the method claimed in Group II may include a step of determining whether a sample has an adequate concentration of cellular matter, the ***total extent*** of the subject matter claimed in Group II is actually a method of classifying a cytological sample based at least in part on such a determination. Claims 30-33 do not positively recite a step of determining cell concentration, and the end result of the method in claims 30-33 is that a sample is classified, not that a cell concentration of the sample is determined. Thus, Group II is not drawn to a method of determining cell concentration.

Similarly, the Examiner's short description of Group III (claims 34-38) as being drawn to "a method of performing an assay to detect human papilloma virus" is incorrect and misleading. While the method claimed in Group III may include a step of designating a sample as satisfactory for performing an assay to detect human papilloma virus (HPV), the ***total extent*** of the subject matter claimed in Group III is actually a method of classifying a cytological sample, which classification of the sample is carried out prior to performing an assay to detect HPV. Claims 34-38 do not positively recite a step of performing an assay to detect HPV, and the end result of the method in claims 34-38 is that a sample is classified, not that an assay to detect HPV is performed. Thus, Group III is not drawn to a method of performing an assay to detect HPV.

Regarding the Examiner's short description of Group I, to the extent that claims 1, 4-15, 21-24, 26, 28 and 29 can be properly described as "a method of determining if a specimen is adequate for cytological slide preparation," Groups II and III may also be described as "a method of determining if a specimen is adequate for cytological slide preparation." In fact, Group II

relates to determining whether a specimen has an adequate concentration of cellular matter needed for performing an intended assay (see claim 30, lines 4-5), which intended assay comprises preparing a slide (see claim 30, lines 10-11). Group III relates to determining whether a sample is satisfactory for performing an assay to detect HPV (see claim 34, lines 6-7 and 9-10), which assay includes withdrawal of an uncontaminated aliquot of the sample prior to preparing a slide (see p. 12, line 25 through p. 13, line 10 of the present specification). According to the description on p. 12, line 25 through p. 13, line 10 of the present specification, if a sample is satisfactory for performing the assay to detect HPV, then the sample is also satisfactory for preparing a slide.

In the Advisory Action, the Examiner did not address Applicants' argument that the Examiner's short descriptions are incorrect and misleading.

Fifth, the Examiner's allegation that some of the subcombinations are separately usable is not correct. Specifically, the Examiner alleges that Group II has a separate utility such as a method for determination of cellular volume. As discussed above, Group II is directed to a method of classifying a sample, not determining cellular concentration. However, assuming *arguendo* that the method claimed in Group II can be used for determination of cellular volume (e.g., assuming that the step of "determining, based on the interrogation, whether the sample has an adequate concentration of cellular matter needed for performing an intended assay" may be construed to include determining cellular volume), the methods in Groups I and III are not precluded from being used in determining cellular volume. For example, in the step in claims 1 and 34 of "determining whether a result of said interrogation meets a criterion," the "criterion" may be "adequate concentration of cellular matter." Thus, to the extent that the Group II method can be used for "determination of cellular volume," determining cellular volume is not a

separate utility of Group II since the Group I and III methods may also be used for determination of cellular volume.

Similarly, the Examiner's allegation that Group III has a separate utility to detect HPV is not correct. As discussed above, Group III is directed to a method of classifying a sample, not detecting HPV. However, assuming *arguendo* that the method claimed in Group III can be used for detecting HPV (e.g., if claim 38 can somehow be construed as including a step of performing the assay to detect the presence or absence of HPV), the methods in Groups I and II are not precluded from being used to detect HPV. For example, the methods in claims 1 and 34 designate the sample as satisfactory for preparing a slide from the sample if the sample meets a criterion (in claim 34, the "criterion" is "adequate concentration of cellular matter"). As described on p. 12, line 25 through p. 13, line 10 of the present specification, a sample designated as satisfactory for preparing a slide may also be satisfactory for withdrawing an aliquot of the sample in order to perform an assay to detect the presence or absence of HPV. Thus, to the extent that the Group III method can be used to detect HPV, detecting HPV is not a ***separate utility*** of Group III since the Group I and II methods may be used for detecting HPV, as well.

In the Advisory Action, the Examiner did not address Applicants' argument that the allegation of some of the subcombinations being separately usable is not correct.

In summary, Applicants have distinctly and specifically pointed out at least the following errors in the restriction requirement: (1) the restriction requirement is not complete, (2) examination of all of the groups would not be burdensome, (3) Groups I, II, and III are not related as subcombinations disclosed as usable together in a single combination, (4) the Examiner's short descriptions of the subject matter in each of Groups I, II and III is inaccurate, and (5) the Examiner's statements that some of the subcombinations are separately usable is inaccurate. As such, Applicants respectfully request withdrawal of the restriction requirement and further request an examination on the merits of claims 30-38.

Respectfully submitted,
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Dated: March 27, 2009

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